UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Iris Markewich, Derivatively, on behalf of Medtronic, Inc.,

Plaintiff,

Civ. No. 08-92 (RHK/AJB)
MEMORANDUM OPINION AND ORDER

v.

Arthur D. Collins, Jr., William A. Hawkins, Richard H. Anderson, David L. Calhoun, Denise M. O'Leary, Kendall J. Powell, Robert C. Pozen, Jack W. Schuler, Michael Demane, Stephen Mahle, Pat Mackin, Susan Alpert, Stephen Oesterle, and Gary Ellis,

Defendants,

-and-

Medtronic, Inc.,

Nominal Defendant.

Gregory M. Nespole, Wolf Haldenstein Adler Freeman & Herz LLP, New York, New York, Garrett D. Blanchfield, Jr., Reinhardt Wendorf & Blanchfield, St. Paul, Minnesota, for Plaintiff.

Jeffrey B. Rudman, Wilmer Cutler Pickering Hale and Dorr LLP, Boston, Massachusetts, Michael G. Bongiorno, Wilmer Cutler Pickering Hale and Dorr LLP, New York, New York, Patrick S. Williams, Briggs and Morgan, PA, Minneapolis, Minnesota, for Defendants and Nominal Defendant.

INTRODUCTION

This derivative action was commenced after Medtronic Incorporated ("Medtronic") voluntarily removed its product, the Sprint Fidelis lead ("the Fidelis lead"), from the market in 2007. Plaintiff, Iris Markewich, on behalf of Medtronic, alleges that certain officers and directors of the company (hereinafter referred to collectively as the "Defendants"), are liable to Medtronic for breach of fiduciary duty, abuse of control, gross mismanagement, insider trading, and aiding and abetting breaches of fiduciary duty. Defendants now move to dismiss. For the reasons described herein, the Court will grant the Motion.

BACKGROUND

The following facts are set forth in the Second Amended Derivative Complaint (the "Complaint"), documents relied upon therein, and documents in the public record. Medtronic is a medical technology business incorporated in Minnesota. (Compl. ¶¶ 3, 37.) Plaintiff is and at all relevant times was an owner of Medtronic stock. (Id. ¶ 36.) Defendants are eight of the eleven members of Medtronic's Board of Directors on the date this action was filed (the "Director Defendants")[1], and six high-ranking executives who are not on the Board of Directors.[2] (Id. ¶¶ 38-54.)

[1] The Director Defendants are: Arthur D. Collins, Jr., William A. Hawkins, Richard H. Anderson, David L. Calhoun, Denise M. O'Leary, Kendall J. Powell, Robert C. Pozen, and Jack W. Schuler. (Id. ¶¶ 38-47.)

[2] These Defendants are: Michael Demane, Stephen Mahle, Pat Mackin, Susan Alpert, Stephen Oesterle, and Gary Ellis. (Id. ¶¶ 48-53.)

A. The Fidelis lead

Medtronic manufactures medical devices, including implantable cardioverter defibrillators ("ICDs"). (Id. ¶¶ 4-5.) ICDs are small devices implanted in patients' chests to monitor heart rates and correct heart rhythm disorders. (Id. ¶ 5.) Complex wires called "leads" connect the ICD to the patient's heart muscle. (Id. ¶ 6.) If a lead detects that the patient's heart is out of rhythm, the ICD sends an electric shock through the lead to correct the problem. (Id.) "If a lead fractures, breaks or otherwise malfunctions, it can deliver unnecessary and frightening shocks, or not operate at all when needed." (Id.)

The Fidelis lead was developed by Medtronic as a "small diameter, high voltage" lead. (Id. ¶ 7.) Soon after its release, the Fidelis lead became the world's most popular. (Bongiorno Decl. Ex. B.) In fact, the Fidelis lead was being used in 90% of Medtronic's new defibrillators. (Compl. ¶ 15.)

Problems with the Fidelis lead began to surface following its introduction to the market. An investigation conducted by a physician at the Minneapolis Heart Institute, Dr. Robert G. Hauser, concluded that the Fidelis lead was failing at a significantly higher rate than expected. (Id. ¶ 9.) The results of this study (hereinafter referred to as the "Hauser Study") were communicated to Medtronic in February 2007 and published in July 2007 in *Heart Rhythm Journal*. (Id.)

The Hauser Study analyzed the failure rate of the Fidelis lead in comparison to the failure rate of another popular Medtronic lead, the Sprint Quattro. (Bongiorno Decl. Ex. D.) The difference in the rates was found to be significant, with the failure rate of the Fidelis lead being ten times greater than that of the Sprint Quattro. (Id.; Compl. ¶ 10.)

However, the Hauser Study noted that as a "single-center study," it may not "reflect experiences at other centers." (Bongiorno Decl. Ex. D.)

In February 2007, Dr. Hauser met with Medtronic to discuss his findings. (Compl. ¶ 101.) Medtronic officials met again with Dr. Hauser in July 2007. (Id. ¶ 112.) At that time Medtronic did not pull the Fidelis lead from the market, determining that it needed to conduct a further statistical analysis. (Id. ¶¶ 112-14; Bongiorno Decl. Ex. B.)

Plaintiff alleges that Defendants were aware that several hospitals and clinics were discontinuing the implantation of the Fidelis lead. (Compl. ¶ 103.) Plaintiff further alleges that Defendants were aware that nearly 600 Fidelis leads had experienced failure and that 679 adverse event reports regarding the Fidelis lead had been filed on the Manufacturers and User Facility Device Experience database ("MAUDE"). (¶¶ 91-92.) Nevertheless, Plaintiff contends that Defendants did nothing to prevent or remedy this situation and instead made fraudulent statements regarding the Fidelis lead. (Id. ¶ 21.)

On October 15, 2007, Medtronic voluntarily recalled the Fidelis lead. (Id. ¶ 23.) The FDA issued a Class I recall that same day. (Id. ¶ 118.) Medtronic stated that its decision to recall the Fidelis lead stemmed from its review of performance data from 25,000 Fidelis leads indicating that the lead was viable in 97.7% of cases, lower than the 99.1% viability rate for the Sprint Quattro. (Id. ¶ 115.) During the recall announcement, Medtronic noted that the recall would cause the company to suffer a revenue loss of $150 to $250 million dollars. (Id. ¶ 116.) After the recall, Medtronic stock fell $6.33 per share, an 11.2% decline. (Id. ¶ 119.)

Plaintiff claims that "Defendants' long inaction in the face of reports of defects in Fidelis Leads is made more egregious by its recent extensive history of regulatory problems and litigation with its cardiac rhythm products." (Mem. in Opp'n at 7.) Specifically, in 2004 and 2005, Medtronic and the FDA issued several recalls of cardio-implant products, some resulting in litigation. (Compl. ¶¶ 67-79.)

B. Infuse

Plaintiff amended her Complaint in October 2008 to add allegations regarding Infuse Bone Graft ("Infuse"), a Medtronic spinal product. (Id. ¶ 1.) As an FDA-approved medical device, Infuse is labeled with a description indicating its approved uses. (Id. ¶ 123.) While a manufacturer may not promote uses of its products other than those described on the label, physicians may use products in ways not listed on the label ("off-label uses"). (Id. ¶¶ 124-25.)

Eighty to ninety-five percent of Infuse use is "off-label." (Id. ¶ 31.) Plaintiff asserts that Defendants knew that Medtronic was illegally paying physicians to endorse and teach off-label uses of Infuse. (Id. ¶¶ 28-30.) In making this assertion, Plaintiff relies on several *qui tam* actions involving Medtronic. (Id. ¶¶ 29-34.) One of these actions alleged that Medtronic paid kickbacks to induce doctors to use its spinal products from 1998 to 2003. (Id. ¶¶ 130-35.) This lawsuit was settled for $40 million dollars with Medtronic disclaiming any wrongdoing. (Bongiorno Decl. Ex. J.) No individual Defendant is named in any of the *qui tam* actions referenced by Plaintiff.[3] (Id. Exs. G-J.)

[3] Recently, Medtronic received a subpoena from the Department of Justice inquiring into the off-label marketing of Infuse. (Nespole Decl. Ex. 4.)

C. The present action

Plaintiff claims that Defendants abandoned their duties with regard to the prudent management of Medtronic by failing to implement policies to ensure Fidelis lead safety, failing to remedy such safety issues once they were discovered, failing to prevent fraudulent statements from being made, illegally trading on inside information, exposing Medtronic to liability for violation of state and federal law, causing Medtronic to be the target of regulatory investigation, failing to prevent the marketing of off-label uses of Infuse, and subjecting Medtronic to reputational harm. (Compl. ¶ 35.) Defendants now move to dismiss.

STANDARD OF DECISION

The Supreme Court case of Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), sets forth the standard to be applied when evaluating a motion to dismiss under Rule 12(b)(6). To avoid dismissal, a complaint must include "enough facts to state a claim to relief that is plausible on its face." Id. at 547. Stated differently, a plaintiff must plead sufficient facts "to provide the 'grounds' of his 'entitle[ment] to relief,' [which] requires more than labels and conclusions, and [for which] a formulaic recitation of the elements of a cause of action will not do." Id. at 555 (citation omitted). Thus, a complaint cannot simply "le[ave] open the possibility that a plaintiff might later establish some 'set of undisclosed facts' to support recovery." Id. at 561 (citation omitted). Rather, the facts set forth in the complaint must be sufficient to "nudge[] the[] claims across the line from conceivable to plausible." Id. at 570.

When reviewing a motion to dismiss, the complaint must be liberally construed, assuming the facts alleged therein as true and drawing all reasonable inferences from those facts in the plaintiff's favor. Id. at 555. A complaint should not be dismissed simply because a court is doubtful that the plaintiff will be able to prove all of the factual allegations contained therein. Id. at 556. Accordingly, a well-pleaded complaint can survive a motion to dismiss "'even if it appears that a recovery is very remote and unlikely.'" Id. (internal quotation marks and citation omitted). Additionally, a derivative plaintiff must plead with particularity: "(A) any effort by the plaintiff to obtain the desired action from the directors or comparable authority and, if necessary, from the shareholders or members; and (B) the reasons for not obtaining the action or not making the effort." Fed. R. Civ. P. 23.1(b)(3).

ANALYSIS

I. Judicial Notice

Defendants have submitted numerous exhibits along with their Motion papers. Plaintiff has moved to strike certain of these materials, all of which are required to be filed with the SEC, on the ground that the information contained therein strays from the four corners of the Complaint. On a motion to dismiss, "[t]he court may consider, in addition to the pleadings, materials embraced by the pleadings and materials that are part of the public record." In re K-tel Int'l, Inc. Sec. Litig., 300 F.3d 881, 889 (8th Cir. 2002) (internal quotation marks and citation omitted). In addition, "public filings required to be filed with the SEC, [can be] considered on a motion to dismiss." Florida State Bd. of

Admin. v. Green Tree Fin. Corp., 270 F.3d 645, 663 (8th Cir. 2001). Therefore, Plaintiff's Motion to Strike is denied.

Plaintiff also seeks judicial notice of several documents she asserts are part of the public record. These documents consist of public commentary made by Medtronic, documents filed with the SEC, news articles, a Corporate Integrity Agreement adopted by Medtronic, and a memorandum of law submitted in a lawsuit filed in the District of Massachusetts. (Nespole Decl. Exs. 1-9.) Defendants do not object to the Court's judicial notice of public statements and SEC filings. To that extent, the Court will grant the Motion. However, the memorandum of law submitted in the District of Massachusetts contains disputed factual assertions. Because disputed facts are not the proper subject for judicial notice, the Court will not consider this document. See Kushner v. Beverly Enters., Inc., 317 F.3d 820, 830 (8th Cir. 2003) (citing Fed. R. Evid. 201(b)). With regard to the news articles, Plaintiff's counsel represented during oral argument that they are not offered for the truth of the matters contained therein, but are offered only to establish the current Department of Justice investigation into Medtronic's marketing of Infuse. To that limited extent, the Court will take judicial notice. Finally, with regard to the Corporate Integrity Agreement, Plaintiff has not established how the content of this agreement is part of the public record. Nevertheless, the Court will consider the document as it does not alter the disposition of the Motion to Dismiss. Accordingly, Plaintiff's Motion for Judicial Notice will be granted in part and denied in part.

II. Failure to make a pre-suit demand

Plaintiff filed this derivative suit without making a pre-suit demand. (Compl. ¶ 156.) Generally, a plaintiff may not bring a lawsuit on behalf of a corporation without first requesting the corporation's board of directors to pursue the action. 19 Am. Jur. 2d *Corporations* § 1961 (2008). Defendants argue that the Complaint must be dismissed for failure to make this demand. The Court agrees.

A. The demand requirement: Minnesota and Delaware law

Minnesota law governs the demand issue as Medtronic is a Minnesota corporation. Kamen v. Kemper Fin. Servs., Inc., 500 U.S. 90, 108-09 (1991). Under Minnesota law, a plaintiff must first make a demand on a corporation's board of directors before filing a derivative action. Winter v. Farmers Educ. & Co-op. Union of Am., 107 N.W.2d 226, 233 (Minn. 1961). The decision to pursue a legal claim on behalf of a corporation involves "the weighing and balancing of legal, ethical, commercial, promotional, public relations, fiscal and other factors familiar to the resolution of many if not most corporate problems." Janssen v. Best & Flanagan, 662 N.W.2d 876, 883 (Minn. 2003) (internal quotation marks and citation omitted). This task "is best done by the board of directors, which is familiar with the appropriate weight to attribute to each factor given the company's product and history." Id.

However, a derivative plaintiff[4] need not make a demand where doing so would be futile. Winter, 107 N.W.2d at 233. "The determination of demand futility is a mixed

[4] A derivative plaintiff is a shareholder bringing a lawsuit "to enforce a corporate cause of action." Price v. Gurney, 324 U.S. 100, 105 (1945).

question of law and fact left to the discretion of the district court." In re Xcel Energy, Inc., 222 F.R.D. 603, 606 (D. Minn. 2004) (Doty, J.) (citing Prof'l Mgmt. Assocs., Inc. v. Cross, 598 N.W.2d 406, 410 (Minn. Ct. App. 1999)). In Winter, the Minnesota Supreme Court discussed demand futility and concluded that a demand is excused only if "it is plain from the circumstances that [demand] would be futile." Winter, 107 N.W.2d at 234 (citation omitted). "[A] demand should be made on the board of directors unless the wrongdoers constitute a majority of the board." Id. at 233. However, Winter does not announce any per se rule that the demand requirement is excused whenever a majority of the board is accused of wrongdoing. To do so would allow any plaintiff to circumvent the demand requirement by merely naming as defendants a majority of a corporation's board. See Lewis v. Graves, 701 F.2d 245, 248-49 (2d Cir. 1983). Instead, Winter made clear that a derivative lawsuit is an "extraordinary remedy" available only when "no other road to redress" is available. Winter, 107 N.W.2d at 233.

Derivative actions are uncommon in Minnesota. See Janssen, 662 N.W.2d at 882 (noting that derivative lawsuits are "not an everyday occurrence in Minnesota's courts"). In fact, the Minnesota Supreme Court has not addressed the issue of demand futility since its 1961 decision in Winter. Therefore, while the Minnesota courts have not expressly adopted Delaware law on the issue of demand futility, this Court has looked to the Delaware courts for guidance in the past. See In re Patterson, Inc. Sec., Derivative & ERISA Litig., 479 F. Supp. 2d 1014, 1038 (D. Minn. 2007) (Doty, J.); In re Xcel Energy,

222 F.R.D. at 606.[5] Nevertheless, the ultimate determination regarding demand futility in this case must have its foundation in the principles outlined in Winter.

The parties agree that the demand futility test described by the Delaware Supreme Court in Rales v. Blasband is relevant here. 634 A.2d 927 (Del. 1993). This test applies in a case "[w]here there is no conscious decision by directors to act or refrain from acting." Id. at 933. Under Rales, a demand is futile when "particularized facts creat[e] a reasonable doubt that a majority of the Board would be disinterested or independent in making a decision on a demand." Id. at 930. A court must determine whether a board "can impartially consider the merits without being influenced by improper considerations." Id. at 934.

B. Plaintiff's claim: a substantial likelihood of personal liability

In the instant case, eight of the fourteen members of Medtronic's Board of Directors (the "Board") are named as defendants. (Compl. ¶¶ 38-46.) Plaintiff's primary argument for demand futility is that a majority of the Board faces a substantial likelihood of personal liability and therefore cannot properly consider a demand.[6] Specifically,

[5] Minnesota courts often look to Delaware for guidance on corporate law issues. See, e.g., In re UnitedHealth Group, Inc. S'holder Derivative Litig., 754 N.W.2d 544, 551 (Minn. 2008) (citing Unitrin, Inc. v. Am. Gen. Corp., 651 A.2d 1361, 1374 (Del. 1995); PJ Acquisition Corp. v. Skoglund, 453 N.W.2d 1, 7 (Minn. 1990) (citing Schreiber v. Bryan, 396 A.2d 512 (Del. Ch. 1978)); Lansky v. NWA, Inc., 471 N.W.2d 713, 714 (Minn. Ct. App. 1991) (citing Tandycrafts, Inc. v. Initio Partners, 562 A.2d 1162 (Del. 1989)).

[6] Plaintiff also asserts that the Board cannot properly consider a demand because the pursuit of the claims "would jeopardize the Company's directors and officers liability insurance coverage." (Compl. ¶ 158.) This argument is without merit. The Delaware Chancery Court has rejected this argument noting that it provides "no particularized facts creating a reasonable doubt that the directors are disinterested or independent." Decker v. Clausen, Civ. A. Nos. 10,684, 10,685, 1989 WL 133617, at *2 (Del. Ch. Nov. 6, 1989).

Plaintiff claims that all Director Defendants are exposed to personal liability for their failure to take preventative or corrective measures with regard to the underlying allegations in the Complaint. Plaintiff further asserts that at least some of the Director Defendants are exposed to personal liability for their illegal insider trading and violation of the federal securities laws. (Compl. ¶¶ 156-67.)

A risk of personal liability can excuse a demand because "a director cannot be expected to exercise his or her independent business judgment without being influenced by the adverse personal consequences resulting from the decision." Rales, 634 A.2d at 936. However, the "mere threat" of personal liability is insufficient as there must be a "substantial likelihood" of personal liability to excuse a demand. Id. (internal quotation marks and citation omitted).

Plaintiff's burden in demonstrating a substantial likelihood of personal liability is made more difficult in this case because Medtronic's Articles of Incorporation contain an exculpation clause. (Bongiorno Decl. Ex. E.) In Minnesota, directors can be liable for the breach of several fiduciary duties, such as the duty of care, the duty of loyalty, and the duty of good faith. Bolander v. Bolander, 703 N.W.2d 529, 556 (Minn. Ct. App. 2005). However, the exculpation clause provides that directors cannot be held "personally liable to the corporation or its shareholders for monetary damages for breach of fiduciary duty . . . [but] can be liable for breach of the duty of loyalty, bad faith acts or omissions, knowing violations of the law, and actions from which they derive an improper personal benefit. (Bongiorno Decl. Ex. E.) Accordingly, Plaintiff cannot save her Complaint with facts supporting an inference of gross negligence, which constitutes a breach of the

exculpated duty of care,[7] but instead has the more difficult burden of pleading a non-exculpated claim to avoid dismissal. See Wood v. Baum, 953 A.2d 136, 141 (Del. 2008); McPadden v. Sidhu, 964 A.2d 1262, 1273-74 (Del. Ch. 2008).

1. Knowing violation of the law

a. Federal securities laws

Plaintiff argues that several Director Defendants are exposed to a substantial likelihood of personal liability because of their knowing violation of the federal securities laws. Specifically, Plaintiff claims these Director Defendants are liable for materially fraudulent statements contained in Medtronic's Form 10-K filed on June 25, 2007. (Mem. in Opp'n at 14-15.) This form was signed by Director Defendants Collins, Anderson, Hawkins, O'Leary, Pozen, and Schuler. (Compl. ¶ 106.) According to Plaintiff, this form materially misrepresents the market acceptance of the Fidelis lead.[8]

For a Director Defendant to be liable for the violation of federal securities law, Plaintiff must demonstrate: (1) misrepresentations or omissions of material fact; (2) causation; (3) scienter; and (4) economic harm. K-tel, 300 F.3d at 888. In this case, the Complaint does not describe any particular piece of non-public information, possessed by the Director Defendants, indicating their knowledge that the 10-K

[7] The "duty of care" is breached when a corporate officer or director displays "reckless indifference to or a deliberate disregard of . . . actions which are without the bounds of reason." Benihana of Tokyo, Inc. v. Benihana, Inc, 891 A.2d 150, 192 (Del. Ch. 2005) (internal quotation marks and citation omitted).

[8] In her brief, Plaintiff states that Defendants made "other public statements," in addition to those in the Form 10-K, that were material misrepresentations. (Mem. in Opp'n at 14.) However, Plaintiff does not make any argument as to why these statements would expose any Director Defendant to a substantial likelihood of personal liability. Therefore, the Court only evaluates the threat of personal liability posed by statements in the Form 10-K.

statements were false. Plaintiff claims that there were "a tidal wave of warnings" indicating that the Fidelis lead was soon to be removed from the market, but Plaintiff does not explain how any Director Defendant would have received these warnings. Therefore, a substantial likelihood of personal liability cannot be established because there is no evidence of scienter.

Moreover, this Court has already determined in a recent securities decision that statements in the June 2007 Form 10-K were not materially false or misleading. In re Medtronic, Inc. Sec. Litig., Civ. No. 07-4564, 2009 WL 649688, at *4-12 (D. Minn. Mar. 10, 2009) (Kyle, J.). The facts alleged in this case are nearly identical to those pleaded in the securities litigation and therefore, the reasoning in that opinion applies here with equal force -- the statements made in the Form 10-K do not create a substantial likelihood of personal liability for any Director Defendant.

b. Department of Justice investigation

Plaintiff alleges that demand is futile in this case because of the Department of Justice investigation into Infuse marketing. (Mem. in Opp'n at 23.) Plaintiff believes that this investigation could uncover information regarding the Director Defendants that will expose them to a substantial likelihood of personal liability. However, this argument is speculative as the Director Defendants cannot face a substantial likelihood of personal liability for unknown conduct that *may* be discovered.[9]

[9] During oral argument, Plaintiff requested the Court not to rule on the present Motion with regard to the Infuse allegations until the Department of Justice investigation is completed. However, the Court will not delay its ruling on this matter in order for Plaintiff to discover additional facts needed to save her claims. Prior to filing the Complaint in this case, Plaintiff

2. Failure to take preventative or corrective measures

Plaintiff claims that the Director Defendants are exposed to a substantial likelihood of personal liability because they "failed to act on fundamental issues at the very core of Medtronic's operations." (Id. at 13.) Specifically, Plaintiff alleges that the Director Defendants knew a recall of the Fidelis lead was necessary months prior to its withdrawal from the market and knew that Medtronic was paying kickbacks to promote the off-label use of Infuse, but "did nothing" to address these issues. (Id. at 14-15)[10] A failure to act in good faith can be shown "where the fiduciary intentionally fails to act in the face of a known duty to act, demonstrating a conscious disregard for his duties." Stone v. Ritter, 911 A.2d 362, 369 (Del. 2006). Such a failure to act in good faith is also a breach of the duty of loyalty. Id. at 369-70.

Delaware courts have recognized that a failure in oversight "is possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment." In re Caremark Int'l Inv. Derivative Litig., 698 A.2d 959, 967 (Del. Ch. 1996). In fact, "only a sustained or systematic failure of the board to exercise oversight -- such as an

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could have inspected Medtronic's books and records to amass a more robust factual predicate to survive a motion to dismiss, but chose not to do so. See Minn. Stat. § 302A.461(4). The Court will not now stay its hand in order to assist the Plaintiff in strengthening her Complaint when she did not exercise due diligence to do so prior to filing this action.

[10] Plaintiffs also claim that Medtronic failed to follow the Heart Rhythm Society Task Force on Device Performance ("HRSTF") Policies and Guidelines. (Mem. in Opp'n at 24-25.) Plaintiff asserts that "[i]f the Director Defendants had made sure that the Company was adhering to this important policy, both they and the public would have had all the necessary information about Fidelis Leads." (Id. at 25.) However, in making this allegation, Plaintiff does not assert that the Director Defendants intentionally shirked the HRSTF policies or were even aware that such policies were not being followed. Therefore, Plaintiff has pleaded at most a breach of the duty of care, an exculpated claim. See Wood, 953 A.2d at 141.

utter failure to attempt to assure a reasonable information and reporting system exists -- will establish the lack of good faith that is a necessary condition to liability." Id. at 971. Thus, liability under this theory is premised "on a showing that the directors were conscious of the fact that they were not doing their jobs." Guttman v. Huang, 823 A.2d 492, 506 (Del. Ch. 2003).

The Complaint does not plead sufficient facts to support the inference of a "sustained or systematic failure" of the Director Defendants to exercise oversight. Directors are entitled to rely on the day-to-day judgments of a corporation's management. See Minn. Stat. § 302A.251(2). Moreover, Plaintiff has not pleaded the Director Defendants' knowledge of the issues they were required to prevent or correct, nor has she pleaded any facts indicating their knowledge of substantial inadequacies in the performance of their oversight duties. See In re Pfizer, Inc. Derivative Sec. Litig., 503 F. Supp. 2d 680, 685 (S.D.N.Y. 2007). In an attempt to establish such knowledge with regard to the Fidelis lead, Plaintiff contends that "warnings came to Medtronic from an array of sources." (Mem. in Opp'n at 16.) Such alleged warnings include:
(1) Medtronic's Product Performance Report indicating that nearly 600 Fidelis leads had experienced failure; (2) the Hauser Study; (3) the discontinuance by several hospitals and clinics of their purchasing of the Fidelis lead; and (4) the 679 adverse event reports related to the Fidelis lead filed in the MAUDE database. (Id. at 16-19.)

These "warnings" do not establish the knowledge of the Director Defendants. "[R]ed flags are only useful when they are either waved in one's face or displayed so that they are visible to the careful observer." Wood, 953 A.2d at 143 (internal quotation

marks and citation omitted). Here, the Complaint does not describe how the red flags were waved in the face of any Director Defendant. Moreover, Plaintiff alleges no "facts suggesting a conscious decision to take no action in response to red flags." In re Forest Labs., Inc. Derivative. Litig., 450 F. Supp. 2d 379, 396 (S.D.N.Y. 2006). Additionally, the Complaint lacks any facts regarding the Director Defendants' roles regarding product safety and efficacy. Certainly, the Director Defendants cannot be liable, under a bad faith or duty of loyalty theory, for their failure to take corrective or preventative action when they were unaware of the issues needing correcting or preventing. In addition, there is no evidence that the Director Defendants were consciously shirking their oversight duties generally.

Plaintiff claims that some Director Defendants were even more likely to have knowledge of the issues surrounding the Fidelis lead and Infuse, and therefore are exposed to a substantial likelihood of personal liability, because of their positions on the Audit Committee and the Technology and Quality Committee. (Mem. in Opp'n at 26-28.) Specifically, Plaintiff argues that "the charters designating the responsibilities of these committees created corporate governance structures designed to prevent exactly the type of wrongdoing complained of" in the Complaint. (Id. at 26.) According to Plaintiff, "[i]t must be assumed that the procedures were followed and the Board decided not to act." (Id.) However, it is well settled that committee membership is an insufficient basis on which to infer knowledge. Wood, 953 A.2d at 142-43; Desimone v. Barrows, 924 A.2d 908, 942 (Del. Ch. 2007). Indeed, "imputing knowledge to a director by virtue of his or her position alone is insufficient for demand excuse purposes." JI v. Van

Heyningen, No. CA 05-273 ML, 2006 WL 2521440, at *12 (D.R.I. Aug. 29, 2006) (citations omitted).

Plaintiff further asserts that the Director Defendants were on "heightened notice" of the issues concerning the Fidelis lead and Infuse because of "prior litigation and enormous payouts arising from similar defects and issues." (Mem. in Opp'n at 20.) With regard to Infuse, Plaintiff contends that Medtronic has a "long history of improper promotion of its bone grafts." (Id.) In order to settle one such suit, Medtronic paid $40 million dollars. (Id. at 21.) With regard to the Fidelis lead, Plaintiff contends that Medtronic has a history of product recalls and related litigation. (Id. at 21-22.) In December 2007, Plaintiff notes that Medtronic paid $114 million dollars to settle lawsuits related to a recall. (Id. at 22.)

These lawsuits do not establish the knowledge of the Director Defendants regarding the challenged conduct in this case. Plaintiff "has not pleaded facts indicating that the challenged settlements were anything other than routine business decisions in the interest of the corporation." White v. Panic, 783 A.2d 543, 553 (Del. 2001). In fact, "the complaint provides no basis to infer the board's assessment of the merits of the suits." Id. Moreover, with regard to the $40 million dollar settlement, Medtronic expressly denied any wrongdoing and no Director Defendant was a defendant in any *qui tam* lawsuit referenced by Plaintiff. (Bongiorno Decl. Exs. G-J.) Accordingly, no inference of knowledge can be made.

Plaintiff further claims that these prior lawsuits "put Defendants on notice that they should be paying attention to problems with defibrillator products and marketing of

bone grafts." (Mem. in Opp'n at 22 n.16.) However, even if this were true, it at most is an allegation of a breach of the duty of care, an exculpated claim. This allegation does not rise to "a sustained or systematic failure of the board to exercise oversight." Caremark, 698 A.2d at 971. Moreover, Plaintiff pleads no facts indicating that the Director Defendants were aware that they were not doing their jobs. See Guttman, 823 A.2d at 506.

In sum, Plaintiff claims that "[a] board may not remain directionless and unresponsive when presented with evidence that management may be failing where it has failed before." (Mem. in Opp'n at 1.) However, "Delaware courts routinely reject the conclusory allegation that because illegal behavior occurred, internal controls must have been deficient, and the board must have known so." Desimone, 924 A.2d at 940. Therefore, no Director Defendant is exposed to a substantial likelihood of personal liability for the bad faith execution of their oversight duties.[11]

3. Insider trading

Plaintiff argues that the illegal insider stock sales of Director Defendants Hawkins and Collins demonstrate demand futility. (Mem. in Opp'n at 29.) In considering this argument, the Court must look to "whether the plaintiffs have pled particularized facts

[11] Plaintiff argues that all of the Defendants in this action "aided and abetted one or more of the other Defendants in breaching fiduciary duties owed to Medtronic." (Compl. ¶ 192.) However, this "conclusory conspiratorial allegation[] do[es] not state with particularity that a majority of the board acted in concert or that demand would have been futile under the circumstances of this case." Patterson, 479 F. Supp. 2d at 1039. In fact, "it is well established that the simple expedient of naming a majority of otherwise disinterested and well motivated directors as defendants and charging them with laxity or conspiracy etc., will not itself satisfy the standards for permitting a shareholder to be excused from demand." Gagliardi v. TriFoods Int'l, Inc., 683 A.2d 1049, 1055 (Del. Ch. 1996).

regarding the directors that create a sufficient likelihood of personal liability because they have engaged in material trading activity at a time when . . . they knew material, non-public information about the company's financial condition." Guttman, 823 A.2d at 502. In addition, the Court must determine whether the plaintiff has pleaded particularized facts showing scienter, or fraudulent intent. Id. at 505. Insider sales "are not inherently suspicious; they become so only when the level of trading is dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from the undisclosed information." Crowell GST Trust v. Possis Med., Inc., 519 F.3d 778, 783 (8th Cir. 2008) (internal quotation marks and citations omitted). Thus, insider trades have to be unusual or suspicious to support an inference of scienter. Green Tree, 270 F.3d at 659.

Plaintiff claims that Hawkins and Collins must have been trading on material inside information because "between November 21, 2006 and October 15, 2008 . . . Defendant Collins' sales were more than seven times, [and] Defendant Hawkins', more than four times, . . . their respective sales during the prior twenty-two month period and, thus, not 'normal or routine.'" (Mem. in Opp'n at 40.) Moreover, Plaintiff claims that such sales were "suspiciously timed," suggesting "knowledge of the stock's artificial inflation." (Id.)[12]

[12] During oral argument, defense counsel noted that this Court has already determined in its recent securities decision that the alleged insider trading of Collins and Hawkins was not unusual or suspicious. In re Medtronic, Inc. Sec. Litig., Civ. No. 07-4564, 2009 WL 649688, at *17-18 (D. Minn. Mar. 10, 2009) (Kyle, J.). The facts alleged here are substantially similar to those pleaded in the securities litigation, and therefore, the reasoning in that opinion weighs heavily against the Plaintiff in this case. During oral argument, Plaintiff did not dispute this assertion, instead arguing that this Court did not rely exclusively on its insider trading findings in the

Plaintiff's allegations of insider trading are conclusory at best. The Complaint lacks any particularized facts "detailing the precise roles that these directors played at the company, [or] the information that would have come to their attention in those roles." Guttman, 823 A.2d at 503.[13] A plaintiff must establish "particularized facts demonstrating defendants possessed material non-public information when the sales were made." Pfizer, 503 F. Supp. 2d at 685-86. The bare allegation that Hawkins and Collins must have possessed such information is insufficient. In re Advanta Corp. Sec. Litig., 180 F.3d 525, 539 (3d Cir. 1999).

Moreover, Plaintiff has not pleaded sufficient facts to otherwise indicate that the stock sales of Collins and Hawkins were unusual or suspicious. "When evaluating stock sales . . . the proportion of shares actually sold by an insider to the volume of shares he could have sold is probative of whether the sale was unusual or suspicious." In re Silicon Graphics, Inc. Sec. Litig., 183 F.3d 970, 986 (9th Cir. 1999). However, Plaintiff has not provided the Court with such percentages, nor has Plaintiff provided the Court with the relevant SEC filings for the relevant time period. Moreover, according to the SEC filings that were provided to the Court by Defendants, many of the stock sales by Collins are explained by his exercise of stock options soon to expire. (Bongiorno Decl. Exs. 2-6.) Stock sales done in conjunction with the exercise of an option are not suspicious. See

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securities action. Thus, it seems the parties agree that the holding in the securities decision is persuasive here. Nevertheless, the Court will address Plaintiff's insider trading allegations.

[13] The Blanchfield Declaration is woefully insufficient in detailing the roles and responsibilities of Collins and Hawkins. This declaration only provides information regarding their compensation, committee membership, and the number of shares sold during the relevant time period. (Blanchfield Decl. Ex. A.)

Campbell v. Lexmark Int'l, Inc., 234 F. Supp. 2d 680, 687 (E.D. Ky. 2002). As to Hawkins, he increased his Medtronic stock holdings between March 21, 2007 and October 15, 2007. (Bongiorno Decl. Exs 7-9.) When insiders increase their stock holdings, it weakens the allegation of insider trading. See Crowell, 519 F.3d at 783.

Finally, Even if Collins and Hawkins did face a substantial likelihood of personal liability for insider trading, such liability would not render a demand futile in this case because no other Board member faces a similar threat. Therefore, a majority of the Board would still be able to properly consider a demand. See Winter, 107 N.W.2d at 233 (requiring that a majority of directors be unable to properly consider demand before it is considered futile).

In conclusion, directors are presumed to be faithful to their fiduciary duties, and therefore, it is also presumed that they would pursue meritorious claims described in a demand. Beam v. Stewart, 845 A.2d 1040, 1048-49 (Del. 2004). Here, it is not "plain from the circumstances that a [demand] would be futile." Winter, 107 N.W.2d at 234. Therefore, Plaintiff was required to make a demand on Medtronic's Board of Directors before pursuing her claims.[14]

III. Leave to replead

Plaintiff has requested leave to replead if her claims are found to be deficient. (Mem. in Opp'n at 35 n.25.) This request was not addressed by Plaintiff at oral

[14] As the Complaint must be dismissed for failure to make a pre-suit demand, the Court need not consider other grounds for dismissal.

arguments, and if granted, the amendment would constitute Plaintiff's third pleading attempt.

The Federal Rules of Civil Procedure provide for liberality in granting leave to amend. Fed. R. Civ. P. 15(a)(2) ("The court should freely give leave when justice so requires.") However, "parties should not be allowed to amend their complaint without showing how the complaint could be amended to save the meritless claim." Wisdom v. First Midwest Bank, 167 F.3d 402, 409 (8th Cir. 1999). In this case, Plaintiff provides the Court with no additional facts and does not discuss how the Complaint will be amended to survive a similar motion to dismiss. Therefore, the Court denies Plaintiff's request to replead.

CONCLUSION

Based on the foregoing, and all the files, records and proceedings herein, **IT IS ORDERED** that: (1) Plaintiff's Motion for Judicial Notice (Doc. No. 47) is **GRANTED** in part and **DENIED** in part; (2) Plaintiff's Motion to Strike (Doc. No. 47) is **DENIED**; and (3) Defendants' Motion to Dismiss (Doc. No. 40) is **GRANTED**, and Plaintiff's Second Amended Derivative Complaint (Doc. No. 37) is **DISMISSED WITHOUT PREJUDICE**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: May 11, 2009

s/Richard H. Kyle
RICHARD H. KYLE
United States District Judge